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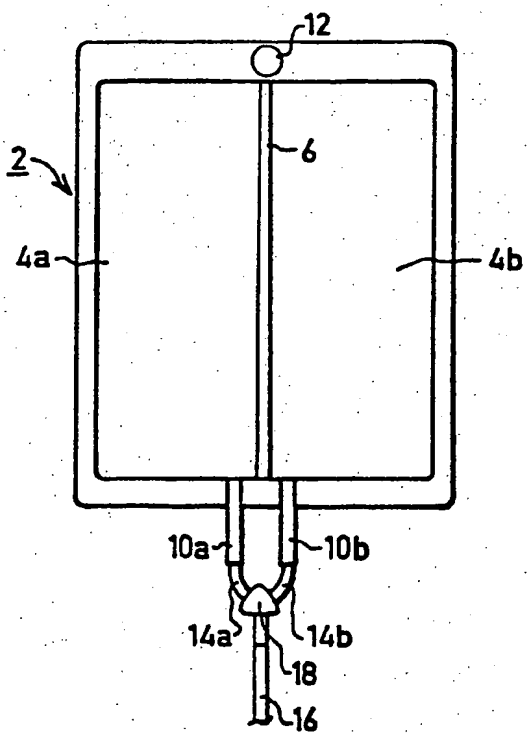
(54) Title: LIQUID MIXING ASSEMBLY FOR PERITONEAL DIALYSIS

(57) Abstract

A liquid mixing assembly (2) for mixing at least two liquids includes a container divided into two (or more) separate compartments (4a, 4b) in side-by-side relation, each for containing one of the liquids. Outlets (10a, 10b) for the compartments are formed in the bottom wall of the container and are joined to a common conduit (16). A blocking device (18) normally blocks liquid flow via any of the outlets (10a, 14a, 10b, 14b) to the common conduit (16), but is manipulatable to unblock liquid flow from all the outlets (10a, 10b, 14a, 14b) simultaneously to the common conduit (16).



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LIQUID MIXING ASSEMBLY FOR PERITONEAL DIALYSIS

The present invention relates to a liquid mixing assembly for mixing two or more liquids together. The invention is particularly useful for mixing solutions for use in various types of perfusion and infusion treatments, especially in peritoneal dialysis, and the invention is therefore described below with respect to this application.

Solutions for use in perfusion and infusion treatments are conventionally stored in flexible, sterilizable plastic bags. These bags generally include inlet and outlet ports, means for hanging the bag above the patient, and tubing, sometimes pre-attached to the bag, for conducting the solution in the bag to the patient.

In certain types of treatments, it is necessary to prepare two or more solutions which must be stored separately, and only mix them at a later stage prior to their administration to the patient. An example of this type of treatment is bicarbonate-buffered peritoneal dialysis, as described by Ing, T.S., et al., Intl. J. of Artificial Organs 8(3) 121-124 (1985), whose contents are hereby incorporated by reference.

Continuous Ambulatory Peritoneal Dialysis (CAPD) is a widely used method of treatment in which a sterile, osmotic solution is introduced, usually by gravity, into the peritoneal cavity, allowed to remain there for several hours, and then replaced by a fresh solution. This type of dialysis can be carried out by the patient himself or herself outside of a medical environment. It is therefore important to provide dialysis equipment which is as user-friendly and mistake-proof as possible.

The dialysis solution is sterilized prior to use, usually by steam autoclave. For various technical and economic reasons, CAPD solutions generally use glucose as the osmotically active agent. Since glucose undergoes caramelization when autoclaved at a neutral or basic pH,

CAPD solutions are usually manufactured at an acidic pH of approximately 5.1-5.5. This low pH, however, can cause problems for the patient such as abdominal pains and suppression of the immune system.

One way to avoid these problems is to prepare an acidic glucose solution, and later neutralize it with a basic solution after both solutions have been separately sterilized. Ing, et al. describe three different methods for implementing this solution.

In one method (the single-container method), the two sterilized solutions are premixed in one container prior to being administered to the patient. This can be done using two separate containers connected to each other, or using a two-compartment plastic bag such as is disclosed in U.S. 4,630,727 to Feriani, et al. This method however is complex as it necessitates two separate operations - mixing and perfusing - in order to perform the dialysis. There can also be a safety problem for the patient if the patient forgets to mix the solutions prior to initiating the dialysis.

The other two methods described by Ing, et al. (the two-stream and three-stream methods) use two separate containers and a roller pump to deliver equal quantities of acidic and basic solutions to a common tube so as to produce the final dialysate on-line. These methods are complicated and cumbersome and are mainly suitable for hospital rather than ambulatory use.

An object of the present invention is to provide a liquid mixing assembly capable of containing two or more liquids in separate, isolated compartments, which can be easily and safely mixed in a single operation by an ambulatory patient for self-administered treatments.

According to the present invention, there is provided a liquid mixing assembly for mixing at least two liquids, comprising: a container divided into at least two separate compartments in side-by-side relation, each for containing one of the liquids, the container including: a bottom wall having an outlet tube for each of the

compartments; a common conduit joined to all the outlets; and a blocking device normally blocking liquid flow from each of the outlet tubes to any other outlet tube or to the common conduit, but manipulatable to permit liquid flow from all the outlet tubes simultaneously to the common conduit.

According to further preferred features of the invention, the container is a plastic bag formed with at least one longitudinal weld line to divide its interior into the at least two separate compartments; also, the common conduit is of a length such that the liquids introduced into one end are thoroughly mixed before emerging from the opposite end.

Such a mixing bag thus allows the user to simultaneously mix the contents of the compartments of the bag and self-administer the mixture in one step.

Multi-compartment bags for use with infusion solutions are well known in the literature. See for example US 4,458,811 to Wilkinson, US 4,997,083 to Loretti, et al, EP 0 132 632 to Abbott Laboratories, DE 3,238,649 to Theuer, and DE 3,830,630 to Fresenius AG. However, in all of the above prior art bags, the separate solutions are first mixed and only afterwards administered to the patient by opening the bag's outlet. As explained above, this adds additional manipulations to the dialysis treatment and introduces a safety problem in the event that the patient neglects to pre-mix the solutions.

By using the bag of the present invention, the number of manipulations required of the patient is no different from the number required during a standard CAPD treatment. The bag is simple to use and needs no special equipment to operate so that it can be used outside a hospital or medical center environment. This is especially advantageous for patients requiring peritoneal dialysis who wish to continue as much as possible with a normal, routine lifestyle. The bag itself will generally be made from a flexible, plastic material which can withstand autoclaving and is chemically inert.

Several embodiments of the invention are described below using various types of blocking devices normally blocking liquid flow but manipulatable to unblock liquid flow from all the outlets simultaneously to the common conduit. One described blocking device is a pinch clamp applied to the juncture of the common conduit with all the outlet tubes. Other described blocking devices comprise a breakaway cannula in each of the outlet tubes and located in side-by-side relation so that all the cannulas may be broken away simultaneously by one manipulation.

The tubing leading from the bag to the patient must be of sufficient length so as to allow thorough mixing of the different solutions. Generally, standard tubing having a length of one meter or more would be used with the bags of the invention, but shorter lengths can be used in particular applications, as can be easily determined by simple experimentation.

It should be emphasized that although the example of CAPD is used in the present description, the invention may be applied in other methods of treatment requiring a plurality of liquids which must be stored separately and mixed before use. The invention is also not limited to two-compartment bags, but could be used with bags having three or more compartments.

Further features and advantages of the invention will be apparent from the description below.

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

Fig. 1 is a plan view illustrating one type of liquid mixing apparatus constructed in accordance with the present invention;

Fig. 2 is a sectional view illustrating one form of blocking device, namely a breakaway cannula, which can be used;

Figs. 3 and 4 are plan views illustrating two types of liquid mixing apparatus constructed in accordance with the present invention including breakaway cannulas as

the blocking device;

Fig. 5 is a front view illustrating one form of housing which may be used with the breakaway cannulas of Fig. 3;

Fig. 6 is a side elevational view of the housing of Fig. 5;

Fig. 7 is a front view illustrating another type of housing which may be used with the breakaway cannula arrangement of Fig. 3;

and Fig. 8 is a side elevational view of the housing of Fig. 7.

Referring to Fig. 1, there is illustrated a mixing bag, generally designated 2, according to one embodiment of the invention. The mixing bag 2 comprises two equal-volumed rectangular compartments 4a and 4b, positioned side by side in parallel to the longitudinal axis of the bag and separated by a longitudinal weld line 6. Each compartment has an outlet 10a, 10b located in its bottom wall adjacent to the longitudinal weld line 6. The bag has a hole 12 centrally in its upper wall for hanging the bag above the patient.

The two outlets 10a, 10b are of equal diameter and length, and have outlet tubes 14a, 14b attached to their external ends. The opposite ends of the outlet tubes are joined to a common conduit 16. An external pinch clamp, shown schematically at 18, blocks or seals the two outlet tubes at their juncture with the common conduit 16, so that normally there is no contact between the liquids in the two compartments and no flow to the common conduit 16.

The function of the bag will be exemplified by a description of its use in peritoneal dialysis. Equal volumes of an acidic glucose solution and a basic buffered solution are introduced into the respective compartments 4a, 4b through the outlets 10a, 10b. The outlet tubes 14a, 14b, conduit 16 and clamp 18 are then connected to the outlets, thereby sealing each compartment. The bag with its contents is sterilized in an autoclave in preparation for use.

When the patient desires to perform a dialysis treatment, the patient simply hangs the bag by the hole 12 above the patient's body, connects the common conduit 16 to a receiving tube leading into the patient's peritoneal cavity, and releases the clamp 18. This simultaneously unblocks the two outlet tubes 14a, 14b so that the solutions flow in equal proportions into the common conduit 16 and thoroughly mix with each other as they pass through the conduit to the patient's peritoneal cavity. The basic solution neutralizes the acidic solution while in the conduit so that the osmotic solution entering the peritoneal cavity is of a neutral pH.

The volumes of the compartments need not be equal, but can be adjusted to the needs of the treatment involved. For example, a small-volume concentrated basic solution can be used together with a large-volume dilute acidic solution. The dimensions of the compartments would then be designed accordingly. The rate of flow out of the compartments can also be controlled by adjusting the relative diameters of the outlets. The diameters of the outlets can be permanently fixed at a predetermined value, or they can be varied using an appropriate variable closure device. Then outlet conduit 16 is of a length such that the two liquids introduced into one end become thoroughly mixed together before reaching the opposite end.

Fig. 2 illustrates the construction of a breakaway cannula, generally designated 18, which may also be used as the blocking device; and Fig. 3 illustrates a further embodiment of the invention in which two such breakaway cannulas 18 are used as the blocking devices for sealing the outlets. Each cannula 18, as shown in Fig. 2, is made of a rigid plastic comprising a short hollow sleeve 20 having an open end 21 and an outer diameter equal to the inner diameter of its respective tube. The opposite end 23 of sleeve 20 is closed by a solid core 22 to define a breakaway handle integrally formed with the sleeve and of smaller diameter than it. A narrowed, short hollow neck 24 joins sleeve 20 of each cannula 18 to its core 22.

In the liquid mixing assembly illustrated in Fig. 3, an outlet tube 26a, 26b, is applied to each of the two outlets 10a, 10b. Each of the outlet tubes 26a, 26b includes one of the breakaway cannulas 18a, 18b described above with respect to Fig. 2, namely a hollow rigid sleeve 20a, 20b closed at one end by a breakaway solid core 22a, 22b, with the breakaway necks 24a, 24b of the two cannulas aligned with each other. The opposite end of the two tubes 26a, 26b are joined to the outlet conduit 16 by a Y-shaped connector 28.

It will thus be seen that, by bending the two outlet tubes 26a, 26b simultaneously, the two cannulas 18 will be simultaneously broken at their necks 24a, 24b, thereby enabling the contents of the two compartments 4a, 4b to flow through the cannulas and Y-shaped connector 28 and to be mixed together in the outlet conduit 16.

Fig. 4 illustrates an arrangement wherein a single dual-branched breakaway cannula 30 is used for conducting the liquid from the two compartments 4a, 4b, via outlets 10a, 10b and outlet tubes 32a, 32b leading to the common outlet tube 16. In this case, the breakaway cannula 30 includes two hollow sleeves (each corresponding to sleeve 20, Fig. 2) normally sealed by a common solid core (corresponding to core 22, Fig. 2) which may be broken away to open the flow simultaneously from both tubes 10a, 10b to the common outlet conduit 16.

Figs. 5 and 6 illustrate one form of housing which may be used in the cannula arrangement of Fig. 3 to facilitate breaking away the two cannulas 18a, 18b simultaneously. Such a housing, generally designated 40, includes a front housing section 41 of rectangular configuration overlying the front side of the two outlet tubes 26a, 26b, and a rear housing section 42 of the same rectangular configuration overlying the rear side of the two outlet tubes. The two housing sections may be secured together on opposite sides of the outlet tubes by hook-shaped clamping elements 43 formed on one section receivable within recesses formed in the other section.

The two housing sections 41, 42, are formed with rectangular cutouts 44 to permit viewing the portions of the outlet tubes 26a, 26b, and particularly the breakaway necks 24a, 24b, of the breakaway cannulas 18a, 18b received in the outlet tubes. In addition, the two housing sections are formed with two grooves 45, 46, aligned with each other and with the breakaway necks of the cannulas.

It will thus be seen that the two cannulas 18a, 18b are received within their respective outlet tubes 26a, 26b, with the breakaway necks 24a, 24b aligned with each other. The two housing sections 41, 42 may then be applied to enclose the outlet tubes 26a, 26b with the housing grooves 45, 46 aligned with the breakaway jaws of the two cannulas.

Normally, the solid cores 22a, 22b of the two breakaway cannulas 18a, 18b would block the flow of liquid from one outlet tube 26a, to the other outlet tube 26b or to the common outlet conduit 16. When it is desired to mix the two liquids, housing 40 would be grasped and bent along the grooves 45, 46 to thereby break away the two cannulas at their breakaway necks 24a, 24b, to permit the liquids to pass from the two outlet tubes 26a, 26b to the common outlet conduit 16.

Figs. 7 and 8 illustrate another form of housing that may be used with the breakaway cannula construction of Fig. 3. In this case, the housing, generally designated 50, is constituted of one side section 51 partially closing one of the outlet tubes 26a, and a second side section 52 partially enclosing the other outlet tube 26b. The two side sections 51, 52 are attached together by fastener pins 53 projecting from one section and received with a friction fit in the other section.

Both housing sections 51, 52 are formed with cutouts 54 extending completely across the respective housing section except for a thin web portion 55 at the side of the housing section. The cutouts 54 are of a size to permit viewing the two cannulas 18a, 18b, and particularly their breakaway necks 24a, 24b between their rigid sleeves

20a, 20b and their solid cores 22a, 22b.

One outlet tube 26a, including one cannula 18 therein, is applied to one housing section 51 with the breakaway jaw 24a aligned with web 55 of that housing secton; and the other outlet tube 26b is applied to the other housing section 52 in a similar manner, with its breakaway jaw 24b aligned with web 55 of that housing section. The two housing sections are then attached by pins 53. Thus, whenever the two liquids are to be mixed, housing 50 is grasped and bent along the thin webs 55 to break away the solid cores of the two cannulas from their respective rigid hollow sleeves, to thereby simultaneously permit the liquid from the two compartments of the bag to flow through their respective outlet tubes 26a, 26b to the common conduit 16.

In all the disclosed embodiments, the common conduit 16 is of a length, e.g., one meter or more, such that the two liquids introduced together into one end of the conduit will be thoroughly mixed before emerging from the opposite end of the conduit into the peritoneal cavity.

While the invention has been described with respect to several preferred embodiments, it is expected that further modifications and applications will be aparent to those skilled in the art.

CLAIMS

1. A liquid mixing assembly for mixing at least two liquids, comprising: a container divided into at least two separate compartments in side-by-side relation, each for containing one of said liquids, said container including: a bottom wall having an outlet tube for each of said compartments; a common conduit joined to all said outlet tubes; and a blocking device normally blocking liquid flow from each of said outlet tubes to any other outlet tube or to said common conduit, but manipulatable to permit liquid flow from all the outlet tubes simultaneously to said common conduit.

2. The liquid mixing assembly according to Claim 1, wherein said container is a plastic bag formed with at least one longitudinal weld line to divide its interior into said at least two separate compartments, and wherein said common conduit is of a length such that the liquids introduced into one end are thoroughly mixed before emerging from the opposite end.

3. The liquid mixing assembly according to Claims 1, wherein said blocking device is a pinch clamp applied to the juncture of said common conduit with all said outlet tubes.

4. The liquid mixing assembly according to Claim 1, wherein said blocking device comprises breakaway cannulas, one in each of said outlet tubes, and all located in side-by-side relation so that all said cannulas may be broken away simultaneously by one manipulation.

5. The liquid mixing assembly according to Claim 4, wherein each of said breakaway cannulas includes a hollow rigid sleeve having an outer diameter equal to the inner diameter of its respective outlet tube, each sleeve having an open end and joined at its opposite end to a solid core which normally blocks the liquid flow to the common conduit, but which may be broken away at its juncture with the hollow rigid sleeve to permit liquid flow to said common conduit.

6. The liquid mixing assembly according to Claim 5, wherein the portions of all the outlet tubes receiving

said breakaway cannulas are enclosed within a housing formed with a bendable weakened portion aligned with the junctures of the hollow rigid sleeves of all said breakaway cannulas with their respective solid cores, permitting bending of the housing along said weakened portion to thereby simultaneously breakaway all said solid cores from their respective hollow rigid sleeves.

7. The liquid mixing assembly according to Claim 6, wherein said container is divided into two separate compartments each including one of said outlet tubes, each outlet tube including one of said breakaway cannulas.

8. The liquid mixing assembly according to Claim 7, wherein said housing includes front and rear housing sections overlying the front and rear sides, respectively, of the outlet tubes, and clamping elements for clamping the two housing sections together; each of said front and rear housing sections being formed with grooves aligned with each other and defining said bendable weakened portion of the housing.

9. The liquid mixing assembly according to Claim 7, wherein said housing includes two side sections each partially enclosing one of said outlet tubes and joined to each other by a plurality of fastener elements; each of said side sections including cutouts interrupted by a web of small dimensions to define said bendable weakened portion of the housing.

10. The liquid mixing assembly according to Claim 7, further including an acid peritoneal dialysis solution in one compartment, and a base peritoneal dialysis solution in the other compartment.

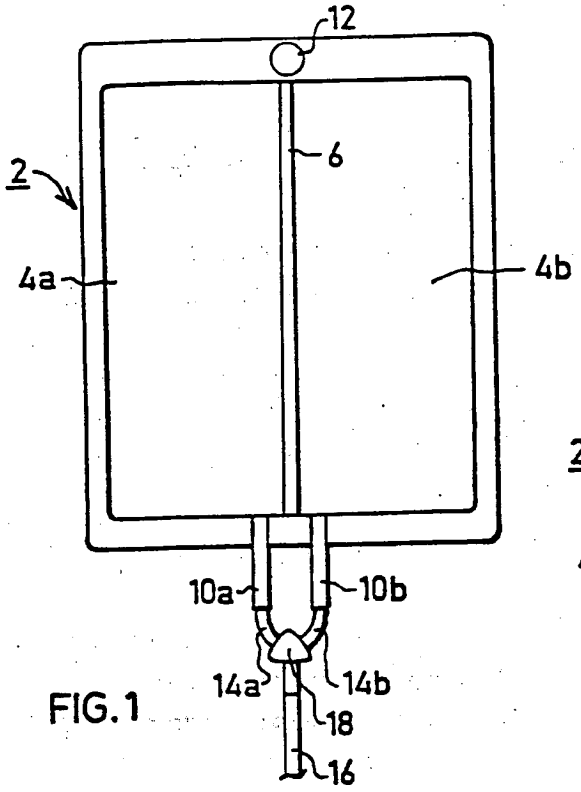

FIG. 1

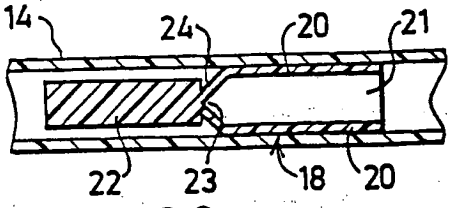

FIG. 2

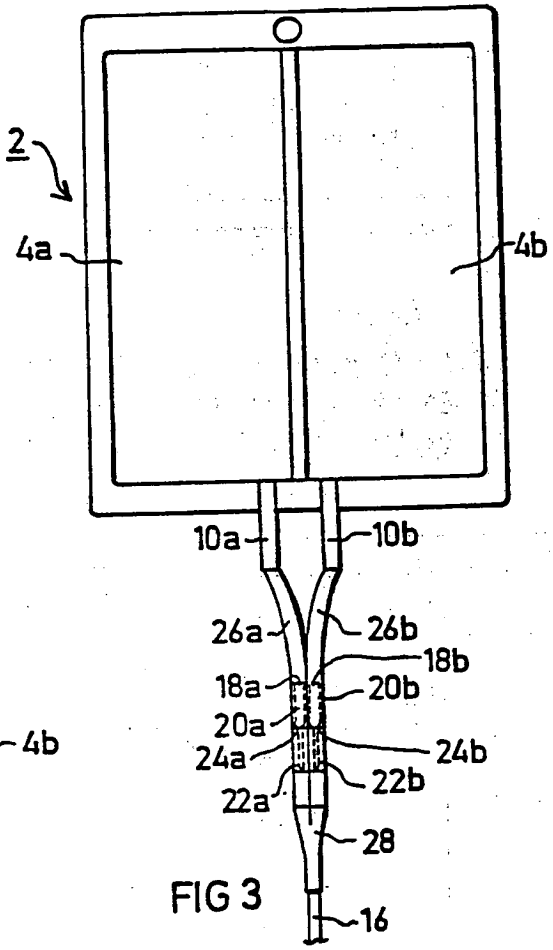

FIG 3

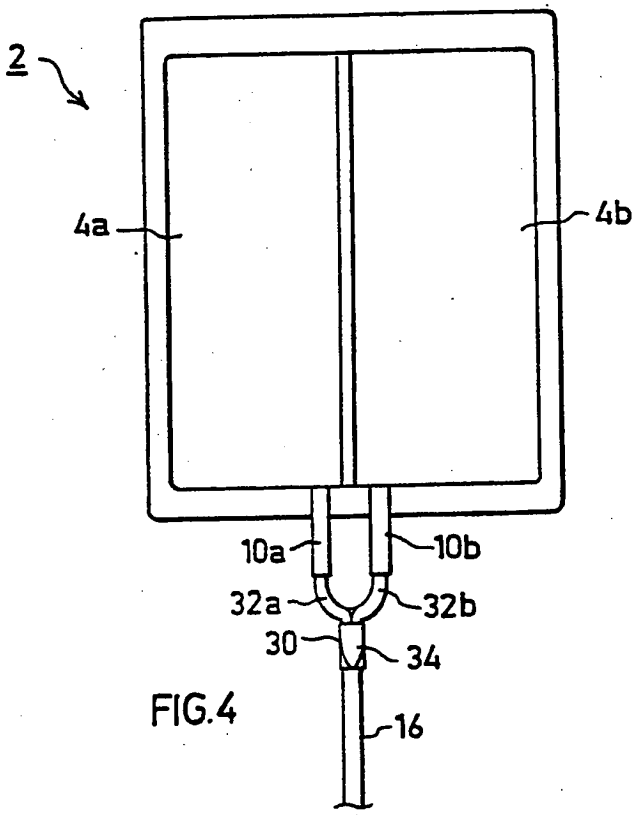

FIG.4

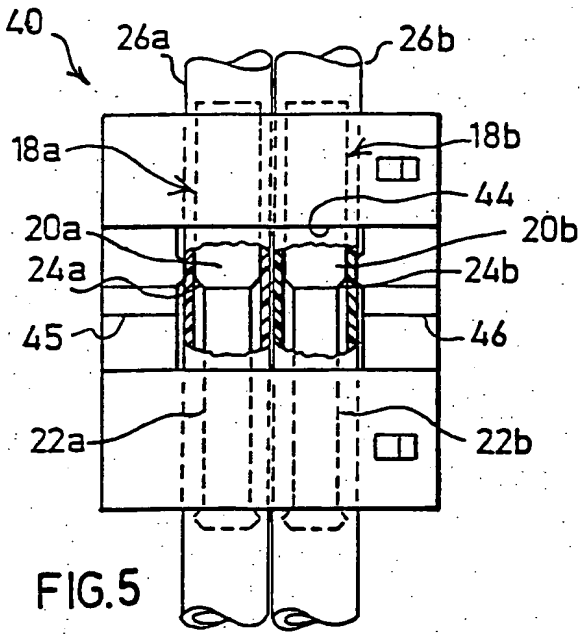

FIG.5

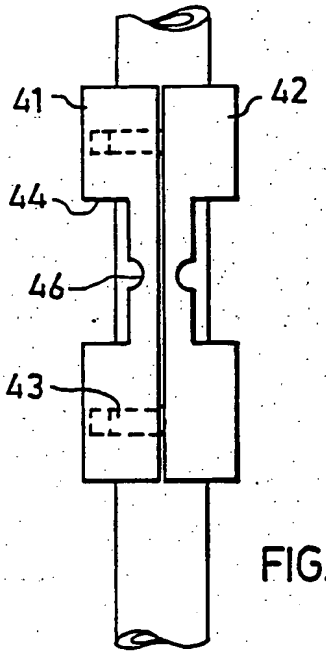

FIG.6

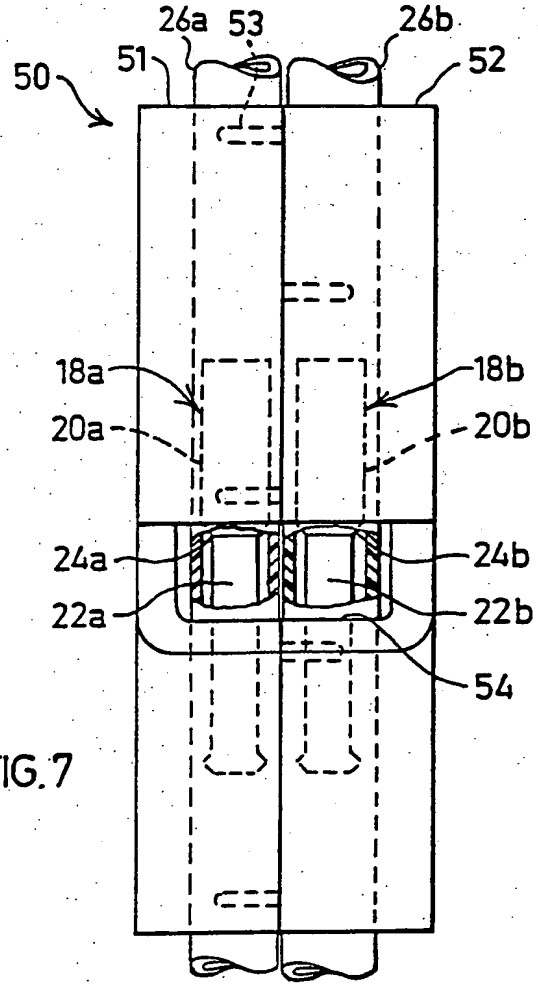

FIG.7

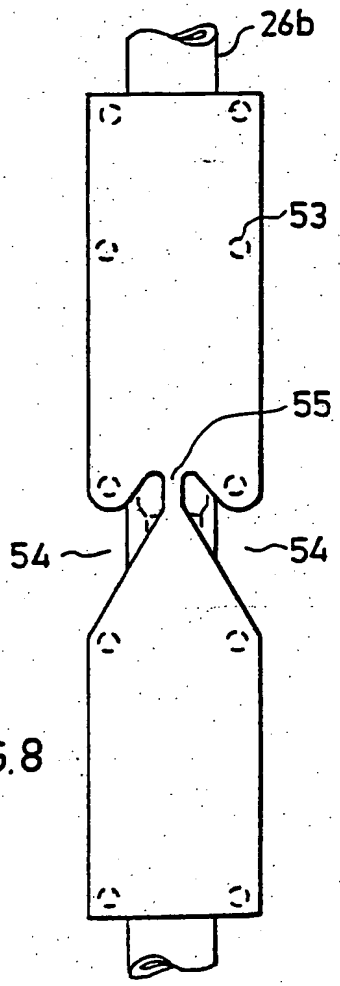

FIG.8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/10738

A. CLASSIFICATION OF SUBJECT MATTER
IPC(5) :A61B 19/00
US CL :604/410
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
U.S. : 604/56, 82, 83, 87, 89-91, 403, 408, 416

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 5,211,643, (REINHARDT ET AL.), 18 May 1993. See Abstract and figures.	1-10
X --- Y	US, A, 4,576,603, (MOSS), 18 March 1986. See the detailed description and the accompanying figures.	1-3 --- 4-10

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